Device for Dilating Esophageal Strictures

Preliminary Design Report

March 3rd, 2006

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ABSTRACT:

The objective of this project is to construct a computer interface compatible with the Alliance™ II Inflation System and CRE™ Fixed Wire Balloon Dilator. The interface will collect esophageal tissue compliance data from esophageal dilations in the form of a pressure versus volume graph. This device should be low cost, safe, easy to use by the client, and capable of producing accurate data. The interface will help our client improve the effectiveness, safety, and speed of the esophageal dilation procedure, allowing patients to have better results with fewer return trips to the hospital.

BACKGROUND:

Problem Statement

The goal of our project is to develop a safer method of treating esophageal strictures. An esophageal stricture is a collection of scar tissue partially blocking the esophagus pathway, thereby limiting food flow and giving the patient a choking sensation. Currently, a pressurized balloon dilation method is used to break the strictures, but can lead to tearing of the esophagus. We intend to instrument the esophageal dilation device to obtain accurate measurements of balloon pressure and volume during dilation. The instrumented system and a computer-readout of the results would be available to the surgeon during the dilation. By measuring the pressure on the esophagus, the surgeon may avoid over-pressurization and prevent tearing the esophagus tissue.

Problem Overview

The design needs to be safe, meaning that it must reduce the frequency of esophageal perforations and emergency surgeries. The dilating apparatus and computer interface must be easy to use and read. Also, this device must provide accurate and reliable information for every procedure. The balloon must be dispensable and low cost, while the inflating gun must be reusable. This device must also measure and monitor stricture compliance via a computer interface during the procedure.

Problem Motivation

The device would reduce the frequency of esophageal perforations compared to the current methods. By measuring the tissue compliance (the flexibility and compressibility of the stricture with respect to pressure and volume) of the stricture as the balloon is inflated, the procedure can be closely monitored as the pressure on the esophagus approaches the perforation point. An audio-visual signal will alert the doctor to abort the procedure to avoid perforation. Knowing the compliance of the stricture would also allow the doctor to adjust the procedure for a specific degree of compliance. If the doctor knows that the stricture is highly compliant, then the stricture can be safely dilated at a faster rate. A highly compliant stricture can also be dilated to a larger

diameter without risk of perforation, therefore decreasing the number of procedures needed to fully dilate the stricture.

Esophageal Strictures

Esophageal strictures are a build-up of scar tissue that results in a narrowing of the distal portion of the esophagus (Figure 1). Strictures are relatively common, affecting two in every 1,000 people [7]. The most common symptom of a stricture is a feeling of choking. Several causes of esophageal strictures are benign fibrous tissue formation, achalasia (the inability of the sphincter muscles to relax), ingestion of caustic agents, gastrointestinal reflux, and cancer [9].

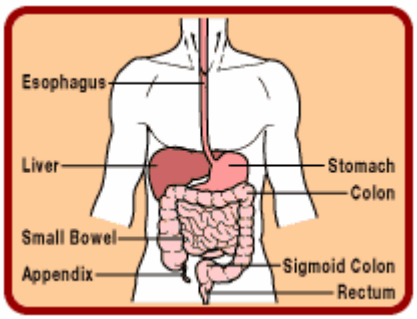

Figure 1. Diagram of the human esophagus anatomy [9].

Treatment for Esophageal Strictures

Treatment options for esophageal strictures are limited to surgery and dilation. There are several different types of surgeries that have been performed to remedy esophageal strictures. These include esophagomyotomy, partial or segmented esophageal resection, esophagoplasty, and mucosal fenestration [2, 11]. However, these surgical procedures are complicated, time consuming, and risky. A more commonly used treatment for esophageal strictures is dilation. Dilating the esophagus involves the use of an inflatable balloon or rubber tube to expand the esophagus (Figure 2).

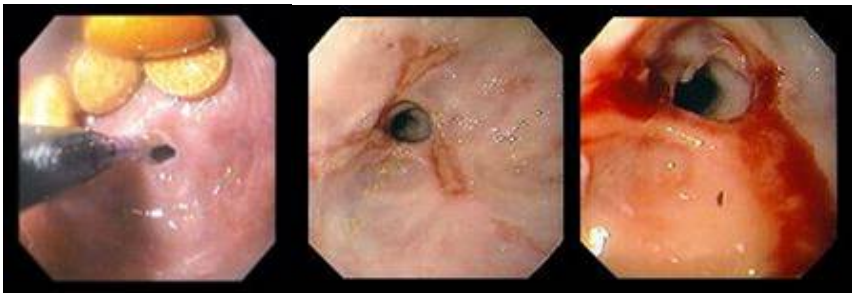

Figure 2. Dilation of a human esophageal stricuture using a balloon dilator [3].

Esophageal Dilators

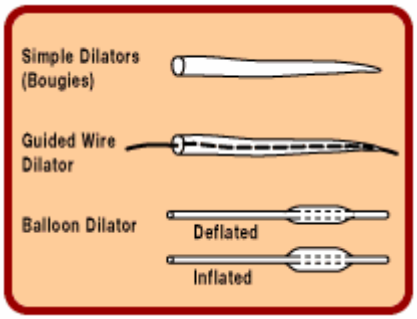

Figure 3. Different types of esophageal dilators [9].

Two different dilators are currently used in the procedure. Mechanical (push-type) dilators exert forces form both the top and the inside of the stricture opening [5]. The Bougie method generally refers to the completely mechanical dilation of strictures. Bougie dilators can also be broken into two categories: those that follow a guide wire and those that do not [1]. Balloon dilators insert a collapsed balloon into the opening of the stricture and then use a manual pump to inflate the balloon. These dilators

must either be passed over a guide wire or through an endoscope (also referred to as TTS for “through the scope”).

The main mechanical dilators include the Hurst, Maloney, Eder-Puestow, and Savary dilators which have evolved with advancements in the field. Maloney dilators contain a mercury-filled center and are largely effective for wider strictures [5]. Another adaptation to the Bougie method is adding the “triple olive” which consists of metal knots in the guide wire to break the stricture. The Eder-Puestow and Savary dilators are inserted into the esophagus using a guide wire. However, the potential for perforation is increased by the use of the wire.

Some balloon dilation methods also work using an over the wire method [5]. These dilators are available as TTS. Balloon dilators are useful for more complex strictures. Theoretically, these dilators would decrease perforation risks and can dilate more intricate strictures. Disadvantages to this method include the higher cost and the reduction of tactile feedback. The latter of these disadvantages provides us with the basis of our project.

Stricture Size and Compliance

Little work has been done to learn more about stricture size and the effects of these various esophageal treatments on the diameter of the esophagus [6]. One study used radiological techniques to measure the stricture size [6]. Their results showed that strictures can vary in elasticity, which makes them difficult to measure. Also, these radiological techniques are only marginally more informative than using endoscopes alone. Esophagrams are typically used to determine the number, location, and length of strictures in the esophagus [8]. However, no work has been done examining tissue compliance in the esophagus or stricture size measurements made by the inflatable catheter balloon.

Design Constraints

The computer interface system must be compatible with the client’s current Alliance™ II Inflation System and CRE™ Fixed Wire Balloon Dilator (see Current Device). This means that any materials attached to the balloon dilator must be non-toxic, flexible, light, and functional inside the human body, which is normally a moist, acidic environment at 37 degrees Celsius. The materials must be durable and capable of withstanding pressures of 6 atm. Furthermore, the device must have smooth surfaces, as rough surfaces will increase the frequency of perforating the esophagus. All components of the device must be secure to eliminate the chance of the patient choking on any dislodged pieces of the device.

This interface also needs to be reusable, durable, and easy to use. The device needs to last for several years and have a low maintenance cost since the electrical and computer components are expensive. The device will be used multiple times a day, varying with the number of esophageal dilations scheduled for the day. Use of the device should require minimal training for the user and should produce accurate data in the form of a pressure versus volume (PV) graph.

Any electrical components used to generate the pressure versus volume graph to measure tissue compliance can not harm the patient. For example, the electric current can not shock the patient, and any wires used must be concealed to prevent perforation of the esophagus lining. Any electrical signals used must obtain accurate PV readings and display a smooth PV curve without interference.

The completed device will need to be tested to ensure that it is safe to use for human diagnosis and that it produces accurate data. Before testing can begin, appropriate protocols and research proposals will need to be written and submitted for approval to the Research Animal Resources Center for animal testing or the Human Institutional Review Board for human studies.

Finally, the budget for this project is limited, which will make procurement of materials difficult. Our client is willing to cover transducer costs, but the other elements of our design will need to be low cost.

Current Device

No devices have been manufactured or designed in research studies collecting esophageal tissue compliance data. However, a biomedical engineering group from 2002 previously worked with our client on a similar project.

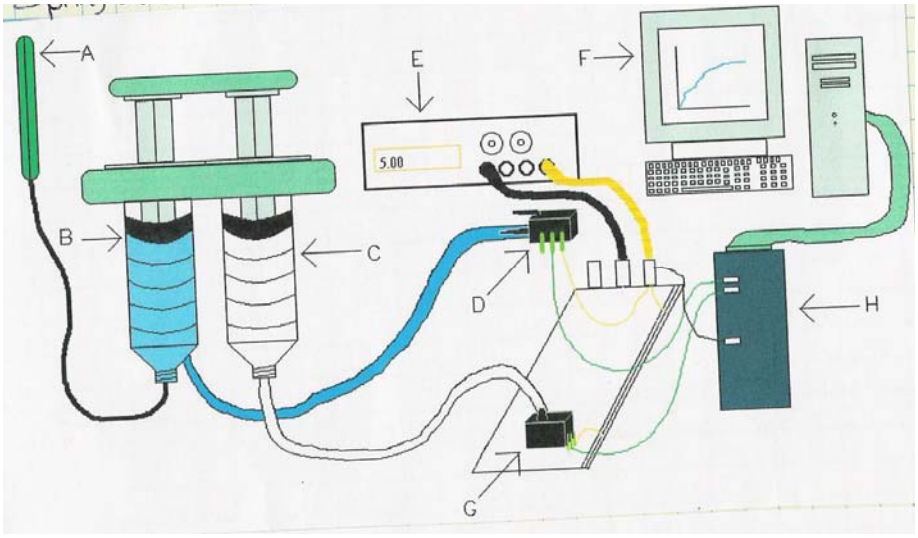

Figure 4. Schematic of prototype from Spring 2002 group: A=Balloon, B=Water-filled syringe, C=Air-filled syringe, D=Differential pressure transducer, E=Power supply, F=Computer output, G=Absolute pressure transducer, H=Biobench interface [10].

The group's final design consisted of two syringes connected to each other. As one syringe was depressed, both syringes would displace equal volumes. The syringes were connected by tubing to a Sensym Inc. pressure transducer. One syringe was filled with water and was connected to a differential pressure sensor to measure the pressure inside the balloon. The second syringe was filled with air and hooked up to an absolute sensor to measure the volume change in the syringe. These sensors were connected to a 5-volt energy source and to ground. The Biobench interface system was then used to

monitor the sensors. Their system was tested once, but the group was unable to differentiate between the pressure being recorded from the balloon and from the esophagus. Also, the pressure-volume graphs generated by their design were not very accurate.

Our computer interface will be designed to collect data from the dilating device currently used by our client. This device consists of a CRE™ Fixed Wire Balloon Dilator (Figure 5) and the Alliance™ II Inflation System (Figure 6) purchased from Boston Scientific.

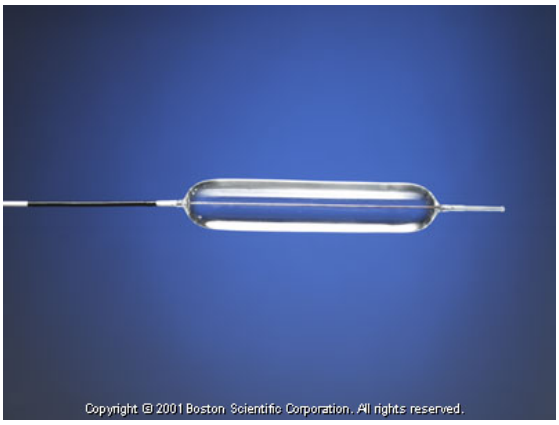

Figure 5. CRE™ Fixed Wire Balloon Dilator [4].

Figure 6. Alliance™ II Inflation System [4].

Competition

The competition for this project is mainly limited to previous research. Previous designs for the surgical equipment provide the only foundation for comparison. No other companies or organizations appear to be heavily researching or investigating alternatives for safer surgical results. Our client admitted his difficulty with receiving funding grants for the project which suggests limited research in the field.

MATERIALS:

Because our project combines the mechanical dilation device with sensors and computers, we have elected to break down the materials list into mechanical and electrical sections for more complete discussion.

Mechanical:

Current dilation devices use the Alliance II Airway Inflation System [4]. The system includes a syringe with an attached pressure gauge, a ratcheted inflation system to normalize the injected volume, and a dilation balloon which is inserted into the esophagus.

Electrical:

In order to create the pressure versus volume curve requested by the client, data needs to be collected and interpreted by a computer program. Based on our final design, a linear position transducer is needed to measure the distance moved by the plunger from the initial position. The computer program will multiply the distance by the cross-sectional area of the centrifuge tube to find the volume, thus generating the PV curve.

Similarly, a pressure transducer will be used in the final prototype to relay the pressure of the balloon to the computer. The volume data must coincide with any readings from the pressure transducer and ultimately produce a graph of the result. LabView will be used to create the computer program.

FUTURE RESEARCH:

No research has been done examining tissue compliance in the esophagus. After completion of our design, an animal protocol and research proposal must be developed in order to proceed with testing. The animals used in testing will be cats or opossums, whose esophageal characteristics closely resemble the human esophagus. This testing must confirm that the device is safe, accurate, and capable of reproducing data.

ALTERNATE DESIGNS:

Linear Position Transducer

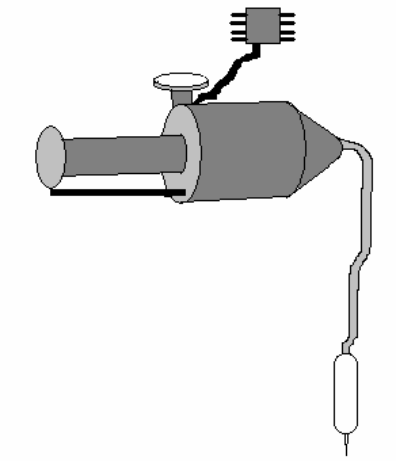

Figure 7. Linear Position Transducer.

The first design is the Linear Position Transducer. In this design, the pump of the syringe would be attached to a linear position transducer. This transducer records the distance that the plunger moves with each consecutive push. Using the position data collected by the transducer, the change in volume can be found. A second transducer would be added near the pressure gauge on the syringe to record the internal fluid pressure. Using the data collected by both transducers, a computer interface program would generate a pressure versus volume curve, allowing doctors to see the pressure on the esophagus before perforation.

The Linear Position Transducer has several advantages. First, adding the pressure transducer requires little or no adjustment to the existing pressure gauge, allowing the user to verify accuracy of computer data. Additionally, this design would be easy for our client to use, produce accurate data, and be the least expensive. This design would also be feasible to construct. However, the only disadvantage to this design is that the linear position transducer may be bulky.

Flow Meter

The second design is the Flow Meter. This design would incorporate a pressure transducer by removal of the current pressure gauge. The transducer would directly record the pressure into a computer interface program and eliminate the need for doctors to manually read the pressure. On the front end of the syringe a flow meter would be attached. This meter would record the volume of the liquid as it passes. The meter would also be connected to a computer interface to electronically record the volume in the syringe and balloon. Using this data, the program would generate a pressure versus volume curve.

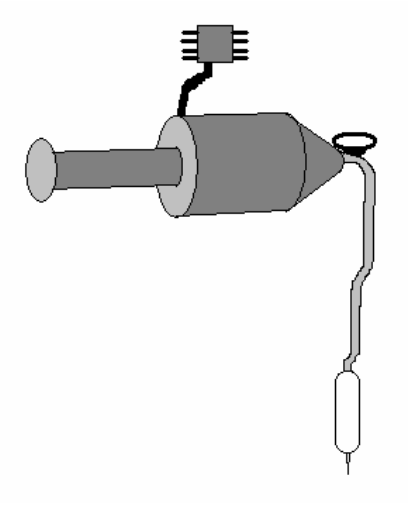

Figure 8. Flow Meter.

The device would be easy for our client to use and produce accurate data. Also, it would be a relatively small device with only a flow meter attached. However, this design would not be feasible to construct unless the flow meter is small. Attaching a flow meter could also reduce the durability of our prototype since the flow meter could be easily broken off from the device..

T-Piece and Laser

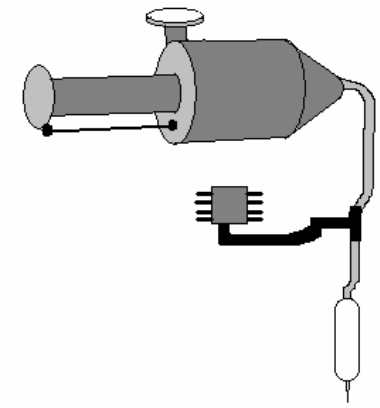

Figure 9. T-Piece and Laser.

The third design is the T-Piece and Laser. This design is similar to the Linear Position Transducer design; however a laser would replace the linear position transducer. As the syringe pump is pressed, the laser would record the distance the pump moves. This distance could be converted into volume of both the syringe and balloon. A pressure transducer would be attached to the tubing connected to the balloon, forming a T-piece junction. Once the data has been collected from both transducers, a computer interface program can generate a pressure versus volume curve.

Although the T-Piece and Laser design would produce accurate data and requires no tampering with the current pressure gauge, it is the least durable and most expensive. Overall, this design is not feasible to construct.

Hand Click

The fourth design is the Hand Click. In this design, a pressure transducer would be added to the pressure gauge. This would electronically record pressure, as well as allow the client to view the pressure. There would be no attachment to record volume. The user would pump a known volume into the syringe each time the handle on the gun is compressed. After each volume increment, the hand click component must be pressed by the user to transmit the volume data to the computer.

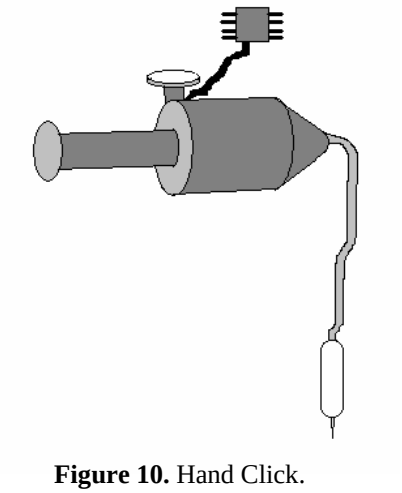

Figure 10. Hand Click.

The Hand Click design is not very practical because it relies on the doctor to record the volume in the syringe and balloon at any known time. Furthermore, the volume and pressure data are collected incrementally and will not create a smooth, continuous PV curve. It would be the least expensive design, but it would not produce accurate data. Overall, this design does not satisfy the client requirements and would not work well.

DESIGN MATRIX:

In this design matrix, accuracy and safety were weighted the heaviest of all the design features because they are most important to the client. Each design was assessed and given a point value for each category in the features column. As shown in the matrix, design one (the linear position transducer design) received the best score.

Feature (Possible Points)	Design 1	Design 2	Design 3	Design 4
Size (5)	4	5	3	4
Ease of Use (6)	6	6	5	2
Cost (12)	9	6	2	10
Accuracy (20)	15	15	15	5
Reproducibility (8)	7	7	7	3
Durability (10)	8	7	5	9
Aesthetics (4)	3	3	3	4
Feasibility (15)	14	5	5	14
Safety (20)	20	20	10	3
TOTALS:	**86**	**74**	**55**	**54**

FUTURE WORK:

We must continue to research the materials that will be used in our main design. Specific research includes looking into cost, accuracy, durability, simplicity, compatibility, and safety of the materials. This includes our pressure transducers, linear position transducers, tubing connections, computer software, and other electrical components needed for circuitry.

We will have to figure out a way to separate tissue compliance from balloon compliance. Since we will be measuring the pressure and volume in the balloon and not the actual force exerted on the balloon from the esophagus, we must eliminate the balloon's effect on the compliance. Further research into how tissue compliance is measured is needed. We will also have to run tests after completion of our prototype to test the accuracy of our compliance measurement.

We have to learn more about circuitry and LabView to build our prototype. Our group has very little experience in circuits and a basic knowledge is needed to hook up the transducers to the computer. Also, our group is unfamiliar with LabView, the program needed to create the computer program. This computer interface must be straightforward and easy to use, as well as provide clear and accurate feedback.

Simulated testing and possibly animal testing will also be done after our prototype is complete. Testing using simulated esophageal tissue, such as liquid latex and plastic tubing, will be needed to test the functionality and accuracy of our prototype. After our prototype is complete and initial tests have been run, animal testing is a possibility. This requires a submitted protocol to the Research Animal Resources Center (RARC) for approval.

APPENDIX A - References

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APPENDIX B

Product Design Specification

Device to Measure Esophageal Strictures

Team: Kristen Seashore, Janelle Anderson, Lynn Murray, Chris Goplen
Date: 2/26/2006

FUNCTION:

The goal of our project is to develop a safer method of treating esophageal strictures. An esophageal stricture is a collection of scar tissue partially blocking the esophagus pathway limiting food flow and giving the patient a choking sensation. Currently, a pressurized balloon dilation method is used to break the strictures, but can lead to tearing of the esophagus. We intend to instrument the esophageal dilation balloon to obtain accurate measurements of balloon pressure and volume during dilation. The instrumented system and a computer-readout of the results would be available to the surgeon during the dilation. By measuring the pressure on the esophagus, the surgeon may avoid over pressurization and prevent the tearing of the esophagus tissue.

CLIENT REQUIREMENTS:

The device must be easy to use by the doctor, safe, low cost, reusable, durable, and transmit accurate graphical data that can be used to measure tissue compliance and stricture size. It must also be approved for use on animals and humans.

DESIGN REQUIREMENTS:

1. Physical and Operational Characteristics
    - a. Performance Requirements
        - i. Reusable
        - ii. Easy to interpret
        - iii. Must be able to undergo sterilization processes
        - iv. Must not affect dilation procedure
    - b. Safety
        - i. Non-toxic and non-allergenic
        - ii. Durable
        - iii. No risk of electrical shock
        - iv. Easy entry and removal from esophagus
    - c. Accuracy and Reliability
        - i. Measure pressure within 0.01atm of actual pressure
        - ii. Measure volume within 0.01mL
    - d. Shelf Life: 2-5 years
    - e. Operating Environment
        - i. Sterile hospital environment

ii. 25°C, standard room temperature

f. Ergonomics
    i. Easy to use
    ii. Low force required to operate device

g. Size
    i. Sensors must fit into esophagus (~25mm)
    ii. Sensors must be able to fit between strictures (1-18mm)
    iii. Device must take up minimal space

h. Weight
    i. Light
    ii. Must not add additional pressure to esophagus tissue

i. Materials
    i. Non-toxic
    ii. Smooth surfaces
    iii. Durable

2. Production Characteristics
    a. Quantity: 1 unit
    b. Target Product Cost: minimal

3. Miscellaneous
    a. Standards and Specifications
        i. Must meet human testing guidelines (FDA)
        ii. Research Animal Resources Center (RARC) certification and approval
    b. Customer/Patient Related Concerns
        i. Easy to use
        ii. Minimal training needed
        iii. Reasonable cost
        iv. Safe
    c. Competition
        i. No designs specifically for monitoring compliance of strictures currently available.